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| APPLICATION NO. | F | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--------------------------------------|---------|--------------|----------------------|---------------------|------------------|--|
| 10/055,836 01/23/2002 | | 01/23/2002 | Richard J. Olson | S63.2-10059 | 7864 | |
| 490 | 7590 | 02/07/2005 | | EXAM | EXAMINER | |
| VIDAS, Al | RRETT & | ESTEINKRAUS, | NGUYE | NGUYEN, VI X | | |
| 6109 BLUE CIRCLE DRIVE SUITE 2000 | | | | ART UNIT | PAPER NUMBER | |
| MINNETO | NKA, MN | 55343-9185 | 3731 | | | |

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | | |
|--|--|--|--|--|--|--|--|
| | 10/055,836 | OLSON, RICHARD J. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Victor X Nguyen | 3731 | | | | | |
| The MAILING DATE of this communication a Period for Reply | ppears on the cover sheet with the c | orrespondence address | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a re - If NO period for reply is specified above, the maximum statutory perions - Failure to reply within the set or extended period for reply will, by stated the second patent term adjustment. See 37 CFR 1.704(b). | N. 1.136(a). In no event, however, may a reply be timely within the statutory minimum of thirty (30) days of will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on 10 November 2004. | | | | | | | |
| 2a)⊠ This action is FINAL. 2b)☐ The | his action is non-final. | | | | | | |
| ·— | | | | | | | |
| Disposition of Claims | | | | | | | |
| 4a) Of the above claim(s) <u>1-22 and 43</u> is/are 5) ☐ Claim(s) is/are allowed. 6) ☒ Claim(s) <u>23,25-27,29 and 32-42</u> is/are reject 7) ☐ Claim(s) is/are objected to. | Claim(s) <u>23,25-27,29 and 32-42</u> is/are rejected. | | | | | | |
| Application Papers | | , | | | | | |
| 9)☐ The specification is objected to by the Exami | iner. | . · · · · | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| • | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for forei a) All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume application from the International Bure * See the attached detailed Office action for a light | ents have been received. ents have been received in Applicati riority documents have been receive eau (PCT Rule 17.2(a)). | on No ed in this National Stage | | | | | |
| Attachment(s) 1) ☑ Notice of References Cited (PTO-892) | 4) 🔲 Interview Summary | | | | | | |
| Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date | Paper No(s)/Mail Do 08) 5) Notice of Informat F 6) Other: | ate Patent Application (PTO-152) | | | | | |

Art Unit: 3731

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 is rejected as being incomplete because it depends from a cancelled claim.

Therefore, it has not been further analyzed on the merit.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23,25-26,29,33-36 and 38-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Di Caprio et al (6,123,712).

Di Caprio et al disclose in figs. 1-2, a stent delivery catheter system is used in PTCA procedures having the limitations as recited in the above listed claims, including: a catheter (13) defines a guide wire lumen (12). A stent (18) is disposed about at least a portion of the distal region of the catheter, where the distal region of the catheter body and the stent define a first diameter region, a second diameter region of the assembly, and where a removable loading tool (11) is disposed about at least a portion of the distal region of the catheter and at least a portion of the proximal region of the catheter, where the tool body has a hollow chamber (10), and where the chamber has an inner surface region (20) which further defines a substantially hollow neck

portion at the proximal end of element 19, where the neck portion comprises a diameter that is tapering from the inner diameter of the first portion to the inner diameter of the second portion (as best seen in fig. 1), and where the hollow chamber defines a first portion containing the first diameter region and where a second portion contains the second diameter region, and where the first opening has a diameter sufficient to allow passage of the catheter assembly having the stent (18) mounted thereon.

Regarding claims 25-26, Di Caprio et al disclose the tool body (11) is arranged to protect the stent from undersired damage during the loading a guidewire into the guide wire lumen (12).

Regarding claims 33-36 and 38-39, Di Caprio et al disclose the tool body (11) is constructed from at least one material of the group consisting of polymer (see col.7, lines 22-31), and where the inner surface region (20) corresponds to at least the portion of the chamber comprising a polymer material

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all 3. obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27 and 37 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Di Caprio et al (6,123,712) in view of Guruwaiya et al (6,251,136).

Di Caprio et al disclose the invention substantially as recited in the claims, but Di Caprio does not disclose the stent comprises a coating which is drug.

Application/Control Number: 10/055,836 Page 4

Art Unit: 3731

Guruwaiya et al teach the stent comprises a coating which is drug (see col. 1, lines 37-44 and col. 3, lines 24-30).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Di Caprio by constructing the stent comprises a coating which is drug as taught by Guruwaiya in order to provide a stent capable of both supporting adequate mechanical loads as well delivering drugs therapy.

Claims 40-42 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Di Caprio et al. Di Caprio et al disclose the invention substantially as recited in the claims, but Di Caprio is silent regarding the inner diameter of the first portion of the inner surface region is about 0.5 mm to about 5 mm. It would have been obvious matter of design choice to modify the inner diameter of the first portion of the inner surface region is about 0.5 mm to about 5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re.Aller, 220F, 2d 454, 105 USPQ 233.

Furthermore, Di Caprio is silent regarding the inner diameter of the second portion of the inner surface region is about 0.2 mm to about 4.9 mm. It would have been obvious matter of design choice to modify the inner diameter of the second portion of the inner surface region is about 0.2 mm to about 4.9 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re.Aller, 220F, 2d 454, 105 USPQ 233.

Response to Arguments

Application/Control Number: 10/055,836 Page 5

Art Unit: 3731

4. Applicant's arguments with respect to claim 23 have been considered but are moot in view of the new ground(s) of rejection. Applicant is asked to please refer to the modified prior art rejection above where examiner addresses applicant's concerns regarding prior art rejection.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 6,077,273 to Euteneuer

U.S. Pat. No. 5,676,654 to Ellis

U.S. Pat. No. 6,149,680 to Shelso

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

Application/Control Number: 10/055,836 Page 6

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen Examiner Art Unit 3731

Vn √N 2/3/2005

JULIAN W. WOO
PRIMARY EXAMINER

Julian W. Moo